the documented safety analysis could be increased;

(2) The possibility of an accident or malfunction of a different type than any evaluated previously in the documented safety analysis could be created;

(3) A margin of safety could be reduced; or

(4) The documented safety analysis may not be bounding or may be otherwise inadequate.

Unreviewed Safety Question process means the mechanism for keeping a safety basis current by reviewing potential unreviewed safety questions, reporting unreviewed safety questions to DOE, and obtaining approval from DOE prior to taking any action that involves an unreviewed safety question.

Use and application provisions means the basic instructions for applying technical safety requirements.

(b) Terms defined in the Act or in 10 CFR Part 820 and not defined in this section of the rule are to be used consistent with the meanings given in the Act or in 10 CFR Part 820.

§ 830.4 General requirements.

(a) No person may take or cause to be taken any action inconsistent with the requirements of this part.

(b) A contractor responsible for a nuclear facility must ensure implementation of, and compliance with, the requirements of this part.

(c) The requirements of this part must be implemented in a manner that provides reasonable assurance of adequate protection of workers, the public, and the environment from adverse consequences, taking into account the work to be performed and the associated hazards.

(d) If there is no contractor for a DOE nuclear facility, DOE must ensure implementation of, and compliance with, the requirements of this part.

§ 830.5 Enforcement.

The requirements in this part are DOE Nuclear Safety Requirements and are subject to enforcement by all appropriate means, including the imposition of civil and criminal penalties in accordance with the provisions of 10 CFR Part 820.

§ 830.6 Recordkeeping.

A contractor must maintain complete and accurate records as necessary to substantiate compliance with the requirements of this part.

§ 830.7 Graded approach.

Where appropriate, a contractor must use a graded approach to implement the requirements of this part, document the basis of the graded approach used, and submit that documentation to DOE. The graded approach may not be used in implementing the unreviewed safety question (USQ) process or in implementing technical safety requirements.

Subpart A—Quality Assurance Requirements

§ 830.120 Scope.

This subpart establishes quality assurance requirements for contractors conducting activities, including providing items or services, that affect, or may affect, nuclear safety of DOE nuclear facilities.

§ 830.121 Quality Assurance Program (QAP).

(a) Contractors conducting activities, including providing items or services, that affect, or may affect, the nuclear safety of DOE nuclear facilities must conduct work in accordance with the Quality Assurance criteria in § 830.122.

(b) The contractor responsible for a DOE nuclear facility must:

(1) Submit a QAP to DOE for approval and regard the QAP as approved 90 days after submittal, unless it is approved or rejected by DOE at an earlier date.

(2) Modify the QAP as directed by DOE.

(3) Annually submit any changes to the DOE-approved QAP to DOE for approval. Justify in the submittal why the changes continue to satisfy the quality assurance requirements.

(4) Conduct work in accordance with the QAP.

(c) The QAP must:

(1) Describe how the quality assurance criteria of § 830.122 are satisfied.

(2) Integrate the quality assurance criteria with the Safety Management

System, or describe how the quality assurance criteria apply to the Safety Management System.

(3) Use voluntary consensus standards in its development and implementation, where practicable and consistent with contractual and regulatory requirements, and identify the standards used.

(4) Describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of § 830.122.

§ 830.122 Quality assurance criteria.

The QAP must address the following management, performance, and assessment criteria:

(a) Criterion 1—Management/Program.

(1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.

(2) Establish management processes, including planning, scheduling, and providing resources for the work.

(b) Criterion 2—Management/Personnel Training and Qualification.

(1) Train and qualify personnel to be capable of performing their assigned work.

(2) Provide continuing training to personnel to maintain their job proficiency.

(c) Criterion 3—Management/Quality Improvement.

(1) Establish and implement processes to detect and prevent quality problems.

(2) Identify, control, and correct items, services, and processes that do not meet established requirements.

(3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.

(4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

(d) Criterion 4—Management/Documents and Records.

(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.

(2) Specify, prepare, review, approve, and maintain records.

(e) Criterion 5—Performance/Work Processes.

(1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.

(2) Identify and control items to ensure their proper use.

(3) Maintain items to prevent their damage, loss, or deterioration.

(4) Calibrate and maintain equipment used for process monitoring or data collection.

(f) Criterion 6—Performance/Design.

(1) Design items and processes using sound engineering/scientific principles and appropriate standards.

(2) Incorporate applicable requirements and design bases in design work and design changes.

(3) Identify and control design interfaces.

(4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.

(5) Verify or validate work before approval and implementation of the design.

(g) Criterion 7—Performance/Procurement.

(1) Procure items and services that meet established requirements and perform as specified.

(2) Evaluate and select prospective suppliers on the basis of specified criteria.

(3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

(h) Criterion 8—Performance/Inspection and Acceptance Testing.

(1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.

(2) Calibrate and maintain equipment used for inspections and tests.

(i) Criterion 9—Assessment/Management Assessment. Ensure managers assess their management processes and identify and correct problems that